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10/569,814	02/28/2006	Takashi Ueno	UENO 12	6639

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EXAMINER	
HIBBERT, CATHERINE S	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/569,814	UENO ET AL.	
	Examiner	Art Unit	
	Catherine S. Hibbert	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a nucleic acid construct having a promoter sequence.

Group II, claim(s) 6, drawn to an RNA.

Group III, claim(s) 7 and 10, drawn to a method of measuring gene expression, the method comprising the step of transcribing an RNA from the nucleic acid construct defined by claim 1 or the vector defined by claim 5.

Group IV, claim(s) 8 and 15, drawn to a method of measuring gene expression, the method comprising the step of contacting a nucleotide molecule with the RNA defined by claim 6.

Group V, claim(s) 9, drawn to a screening method for a functional nucleotide molecule that alters expression of a target gene, the method comprising the step of detecting an activity of altering expression of a target gene by a functional nucleotide molecule according to the method defined by claim 7.

Group VI, claim(s) 14, drawn to a screening method for a functional nucleotide molecule that alters expression of a target gene, the method comprising the step of detecting an activity of altering expression of a target gene by a functional nucleotide molecule according to the method defined by claim 8.

Group VII, claim(s) 11 and 13, drawn to a screening method for a gene whose expression is altered by a nucleotide molecule, the method comprising the step of transcribing an RNA from the nucleic acid defined by claim 1.

Group VIII, claim(s) 12 and 16, drawn to a screening method for a gene whose expression is altered by a nucleotide molecule, the method comprising the step of contacting a nucleotide molecule with the RNA defined by claim 6.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claimed nucleic acid construct having a promoter sequence, at least one protein-encoding nucleotide sequence linked to the promoter sequence in a translatable state, and a poly A signal sequence, wherein the nucleic acid construct further contains, between the promoter sequence and the poly A signal sequence , a nontranslatable nucleotide sequence that is different from the protein-encoding nucleotide sequence, (the protein-encoding nucleotide sequence linked to the promoter sequence in a translatable state and the nontranslatable nucleotide sequence that is different from the protein-encoding nucleotide sequence being linked together so that they are transcribed from the nucleic acid construct in a single RNA molecule), and the nontranslatable nucleotide sequence consisting of either (1) a nucleotide sequence that encodes a protein or a part of the protein; or (2) a nucleotide sequence of an untranslated region that is naturally located on the 5' or 3' side of a nucleotide sequence that encodes a protein, (Claim 1) does not represent an advance over the art (see especially page 603, Figure 1 legend, Yokota et al. in "Inhibition of intracellular hepatitis C virus replication by synthetic and vector-derived small interfering RNAs" (EMBO reports Vol. 4, No. 6, 2003) or Pachuk, C.J. in

"Methods and Constructs for Evaluation of RNAi Targets and Effector Molecules"

(WO2004/076629), cited in search report) and hence there is no unity of invention.

The compositions of Group I and II are distinct as each is defined by distinct features, i.e. nucleic acid construct having a promoter sequence (encompasses DNA molecules having promoter sequences) versus RNA molecule (encompasses RNA molecules that do not have a promoter sequence). The methods of Groups III- VIII are distinct each from the other because each uses different, unrelated, method steps. The methods of Groups III vs. IV, V vs. VI, and VII vs. VIII are distinct as each uses a distinct composition, i.e. nucleic acid construct having a promoter sequence of Group I versus RNA molecule of Group II. Furthermore, the Groups III-IV are methods of measuring gene expression, whereas the Groups V-VI are screening methods to detect a functional nucleic acid molecule that alters gene expression of a target gene, whereas the Groups VII-VIII are screening methods to detect a gene whose expression is altered by a nucleic acid molecule. In addition, the compositions of Groups I and II can be used in different methods. For example, the composition of Group I can be used for transcription of RNA molecules, making recombinant DNA molecules, and as templates for pCR probe reactions versus the composition of Group II can be used in an unrelated method such as a substrate for ribonuclease assays.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to

another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.

103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
This application contains claims directed to the following patentably distinct species:

-If Applicant elects Group I, III, V, or VII,

-Applicant must further elect only one type of nontranslatable nucleotide sequence from among the group consisting of: "a nucleotide sequence that encodes a protein or a part of the protein"; and "a nucleotide sequence of an untranslated region that is naturally located on the 5' or 3' side of a nucleotide sequence that encodes a protein" (e.g. see claim 1).

-Applicant must further elect only one type of nucleic acid construct from between the mutually exclusive species recited in Claims 2 and 3.

-If Applicant elects Group II, IV, VI, or VIII,

-Applicant must further elect only one type of nucleotide sequence from between the group consisting of type (1) and type (2) as shown in Claim 6.

-If Applicant elects Groups III, IV, VII, or VIII,

-Applicant must further elect only one type of system from between the mutually exclusive species of "cell" or "cell-free" system.

-If Applicant elects Groups III or V,

-Applicant must further elect only one type of nontranslatable nucleotide sequence from among the group consisting of: "a nucleotide sequence that encodes a protein in a target gene", "a part of the nucleotide sequence", and "an untranslated region that is located on the 5' or 3' side of a nucleotide sequence that encodes the protein in the target gene" (e.g. see claim 7).

-If Applicant elects Groups IV, or VI,

-Applicant must further elect only one type of nontranslatable nucleotide sequence from among the group consisting of: "a nucleotide sequence that encodes a protein in a target gene", "a part of the nucleotide sequence", and "an untranslated region that is located on the 5' or 3' side of a nucleotide sequence that encodes the protein in the target gene" (e.g. see claim 8).

-If Applicant elects Groups VII,

-Applicant must further elect only one type of nontranslatable nucleotide sequence from among the group consisting of: "a nucleotide sequence that encodes a protein in an arbitrary gene", "a part of the nucleotide sequence", and "an untranslated region that is located on the 5' or 3' side of a nucleotide sequence that encodes the protein" (e.g. see claim 11).

-If Applicant elects Groups VIII,

-Applicant must further elect only one type of nontranslatable nucleotide sequence from among the group consisting of: "a nucleotide sequence that encodes a protein in an arbitrary gene", "a part of the nucleotide sequence", and "an untranslated region that is located on the 5' or 3' side of a nucleotide sequence that encodes the protein" (e.g. see claim 12).

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons given above.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert, Ph.D., whose telephone number is 571-270-3053. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catherine S. Hibbert
Examiner/AU1636

/Daniel M Sullivan/
Primary Examiner, Art Unit 1636